K121824

Section 5: 510(k) Summary

AUG 2 3 2012

5.1. Submitter:

Lascod Spa.
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Florance, Italy
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5.2. Contact:

Gualtiero Cozzi
General Manager
Phone: +39 055 4215768
Email: fiesoli@lascod.it

5.3. Date of Summary:

June18, 2012

5.4. Device:

Common Name: Chromatic Alginate
Trade / Proprietary name: Kromopan
Classification Name: Material, Impression

Common Name: Chromatic Alginate
Trade / Proprietary name: Alginor
Classification Name: Material, Impression

Common Name: Chromatic Alginate
Trade/ Proprietary name: Alginelle type 1
Classification Name: Material, Impression

Common Name: Chromatic Alginate
Trade/ Proprietary name: Alginelle type 2
Classification Name: Material, Impression

Common Name: Chromatic Alginate
Trade/ Proprietary name: Millenium
Classification Name: Material, Impression

5.5. Predicate Devices:

Manufacturer: Lascod Spa, Italy.
Device: Kromopan 1
510(k) Number: Pre-amendments Device
Classification Names & Citations:
21 FR 872.3660, Impression Material, Class 2

Manufacturer: Lascod Spa, Italy.
Device: Kromopan 2
510(k) Number: Pre-amendments Device
Classification Names & Citations:
21 CFR 872.3660, Impression Material, Class 2

5.6. Intended Use:

Kromopan type 1, Kromopan type 2, Alginor type 1, Alginelle type 1, Alginelle type 2 and Millenium alginates are irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define the required interventions and/or check their effectiveness. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.

5.6. Substantial Equivalence Summary:

This submission is based on the preamendments device Kromopan. Alginor, Alginelle and Millenium are substantially equivalent to Kromopan because they all have the same intended use and are nearly identical in their chemical composition.

5.7. Technological Characteristics

All the alginates described in the premarket notification application (510k) have the following technological characteristics:

- Identical mechanism of action
- Identical dimensional stability 100 hours
- Highly similar preparation times
- Highly similar elastic recovery and accuracy

5.8. All LASCOD alginates comply with the recognized International Standards Organization guidance. Specifically the Powder with ISO 1563:1990- 4.1 / 6.2, Mixed material with ISO 1563:1990 - 4.3 / 6.2, Mixing Time ISO 1563:1990 – 4.4, Total working time ISO 1563:1990 -4.5 /6.3, Reproduction of detail ISO 1563:1990 -4.6 /6.4, Recovery from deformation ISO 1563:1990 – 4.7 / 6.5, Strain in compression ISO 1563:1990 - 4.8 / 6.6, Compressive strength ISO 1563:1990- 4.9./6.7.

Additionally, these Alginates also comply with the following LASCOD performance criteria: LAVSCOD PVPF001 -3.8(setting time), -3.3 (first color change & second color change), -3.11(dimensional stability), -3.5 (Flavor), and -3.6 (color after setting time).

5.9. LASCOD will update and include in this summary any other information deemed reasonably necessary by the FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 2 3 2012

LASCOD SpA
C/O Mr. Blix Winston, MPA, MS
ACMD Consulting, Limited Liability Company
2600 Mullinix Mill Road
Mount Airy, Maryland 21771

Re: K121824
Trade/Device Names: Kromopan (type 1 and 2), Alginor (type 1), Alginelle (type 1 and 2), and Millenium
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: June 18, 2012
Received: June 21, 2012

Dear Mr. Winston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121824

Device Name: Kromopan type 1 and 2, Alginor type 1, Alginelle type 1 and 2, Alginelle type 2, and Millenium

Indications for Use:

Kromopan type 1 and 2, Alginor type 1, Alginelle type 1, Alginelle type 2 and Millenium alginates are irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define the required interventions and/or check their effectiveness. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.

Prescription Use ___X___ AND/OR Over-The- Counter Use _____

(Part 21 CFR 810 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121824